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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,498	03/29/2001	Eileen C. Fuchs	112701-200	5214

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EXAMINER	
PRATT, HELEN F	

ART UNIT	PAPER NUMBER
1761	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/821,498	FUCHS ET AL.
	Examiner	Art Unit
	Helen F. Pratt	1761

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 1 and 15 are objected to because of the following informalities: in claim 1, line 7, "monosaturated" should be "monounsaturated" and also line 7, there should be a comma after "fatty acids". In claim 15, last line "muscle less" should be "muscle loss". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-12, 15-23, 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mark et al. in view of Whitney et al. and further in view of Alexander (5,231,085).

Mark et al. disclose a method of administering a therapeutic composition. containing protein, in the amount of 15-20 % which can be hydrolyzed whey protein (col. 3, lines 35-55) (with 100% being from hydrolyzed whey protein as in claim 4), a lipid source which can be omega-6 to omega-3 ratio of 7:1 in the amount of 20-50% which reads on "at least 18%" of the lipid source (col. 4, lines 34-47), vitamins and minerals which are known to include C and E (col. 4, lines 48-47-54 and col. 6, lines 55-68 and col. 7, lines 5-30) and a carbohydrate source such as maltodextrin, corn starch, sucrose and corn syrup (col. 4, lines 6-14). The reference discloses that the amount of

protein in the composition is optimal for moderate tissue repair needed of the targeted population (col. 3, lines 35-45). Claims 1 - 4, 6, 9-12 differ from the reference in whether the composition is for "improving muscle protein synthesis. However, the claimed ingredients have been shown in the claimed amounts, therefore protein synthesis must have been improved using the claimed composition. In addition, Whitney et al. disclose that it is known that muscles are made of protein and that particular amounts of protein are designed to cover the need to replace protein containing tissue which is lost (page 178, col. 2 2nd complete para. and pages 138, 139 (Protein RDA). Therefore, it would have been obvious to make a composition to improve muscle protein synthesis because the reference to Mark discloses that the claimed composition is known, and Whitney discloses that protein which is part of the claimed composition is necessary for muscle building along with carbohydrates (breads, cereals fruits vegetables) and minerals found also therein (page 179, 1st col. 2nd para.).

Claim 1 has been amended to require at least 40% monounsaturated fatty acids MUFA's. However, the specification does not say that this is a critical limitation or what the function of this amount of MUFA's would be. It is seen at this time that the claimed amount of MUFA's is found in the particular types of oils cited, i. e. canola, corn, soy and milk fat and soybean oil (col. 4, lines 34-40) because the Patent Office does not have the facilities to shown that they do not, and MUFA's are known to be present in particular amounts in all these fats. Also, Alexander discloses the use of 1-30 g. of MUFA's, which would have been 40% of total structured lipids (col. 6, lines 11-20, col. 13, lines 40-41). Therefore, it would have been obvious to use a particular amount of

MUFA's for their known health promoting characteristics in the above combination of references.

Claim 7 further requires particular amounts of monounsaturated fatty acids and polyunsaturated fatty acids and claim 8 particular amounts of saturated fatty acids. Mark et al. disclose the use of canola oil, corn oil and soybean oil all of which contain both mono and polyunsaturated fatty acids. The particular amounts are seen as within the skill of the ordinary worker, as the beneficial effects of the oils are well known, absent any unexpected results using the particular amounts of oils. Certainly, in these oils the amount of saturated fatty acids would have bee less than 30%. Therefore, it would have been obvious to use known oils in particular amounts in the claimed composition.

The limitations of claims 15-23, 26-34 have been disclosed above and are obvious for those reasons. Any various in amounts are seen as within the skill of the ordinary worker. Also as in claim 15 muscle loss would also be prevented by providing protein, which builds muscle (Whitney et al., supra). Claim 15 has been amended to require that the individual is at risk of muscle loss. However, in a metabolically stressed patient, a person would have been at risk for muscle loss, hence the use of an increased caloric density in the composition (abstract) and the same would be pertinent to requiring accelerated muscle mass recovery since increased calories, and the addition of protein would have promoted both. Therefore, it would have been obvious to make a composition as claimed as shown by the combined references which would

prevent muscle loss, as Whitney et al. disclose that muscles are made of protein, and protein is supplied by the composition in the claimed amounts.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mark et al. in view of Whitney et al. as applied to claims 1-4, 6-12,15-23, 26-34 above, and further in view of Ballevre et al. or Kawasaki et al. and Etzel.

Ballevre et al. disclose a protein composition containing caseinoglyco-macropeptide (GMP), which can be used in a nutritional supplement (col. 12, lines 20-21, lines 40-60). Also, Kawasaki et al. disclose that it is known to use GMP's in the field of food and medical supplies (col. 5, lines 60-64). Etzel disclose that it is known to use GMP as a nutraceutical in foods and in medicine (col. 1, lines 25-35). As GMP is a type of protein and muscles are known to be made of proteins and the function of eating protein is to make muscle tissue, it would have been obvious to use GMP for this function. Additionally the GMP is made from whey protein as in claim 1 and is said to be a neutraceutical with higher nutritional and functional properties because of the trend towards foods with enhanced health benefits, lower fat content and lower lactose content (Etzel, col. 3, lines 38-44, col. 11, lines 65- 66). Nothing critical has been shown in the use of GMP, but only that it can be combined with whey protein hydrolysate (page 4, 3rd para. of specification). Therefore, it would have been obvious to use GMP in the composition of Mark et al. for its known function of providing another source of hydrolyzed protein.

Claims 13, 14, 24, 25, 35, 36 are rejected under 35 U.S.C. 103(e) as being unpatentable over Mark et al. in view of Whitney as applied to claims 1-4, 6-12, 15-23, 26-34 above, and further in view of Cavaliere et al.

Claim 13 further requires various kinds of prebiotic fiber. Cavaliere et al. 6,326,000 disclose a composition containing bifidobacterium and fiber such as inulin and oligosaccharides (abstract and col. 5, lines 40-55). Often when people are ill, and have been taking antibiotics, the bacterial flora in the intestine have been killed off by the antibiotic (col. 2, lines 25-33). The bifidobacterium and fiber play a role in replacing the bacterial flora. Nothing has been shown in applicant's specification, that the use of the prebiotic fiber actually helps in improving muscle protein synthesis, or in preventing muscle loss so the prebiotic fiber, it must be used just as the vitamins are used for their particular known functions. Therefore, it would have been obvious to add prebiotics to the composition for their known function of increasing the bacteria in the intestine to increase overall health.

ARGUMENTS

Applicant's arguments filed 7-26-04 have been fully considered but they are not persuasive. Applicants argue that Mark does not disclose the claimed amount of MUFA's. However, no criticality is seen at this time in the new limitation.

Applicants argue that Mark et al. is to metabolically stressed patients and that the present claims are to improved muscle protein synthesis, accelerated muscle mass recovery and that Mark does not mention the word "muscle". However, as the composition has been shown, and protein is known to promote muscle synthesis, as

this is one of the functions of protein in the diet, then additional muscle mass would have occurred. Mark et al. discloses that " patients suffering from loss of nutrients require adequate nutritional support " and that a lack of nutritional support can result in malnutrition associated complications and that the goal of nutritional support is to maintain the body mass (col. 1, lines 10-19). Certainly, body mass includes muscle mass and the function of protein is to maintain and develop such (see Whitney, page 178, col. 2, 2nd complete para. and pages 138 and 139 as cited previously). Further limitations as in "for improving muscle protein synthesis" are seen as intended uses and are not given weight in composition claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 571-272-1404. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Milton Cano, can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Hp 9-6-04

H. Pratt

HELEN PRATT
PRIMARY EXAMINER